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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Chris Cicens

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

NGUYEN, HUONG Q

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/732,843	Applicant(s) CICENAS ET AL.	
	Examiner Helen Nguyen	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is responsive to the amendment filed 7/14/2006. Claims 1, 16, and 17 have been amended. **Claims 1-20** remain pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1-13, 16-20** are rejected under 35 U.S.C. 102(b) as being anticipated by Burbank et al (US Pat No. 5526822).

4. In regards to **Claim 1-2**, Burbank et al disclose a biopsy device comprising of a hollow biopsy needle (44) having a tissue receiving port (46), a hollow cutter (68) advanceable within the biopsy needle to sever tissue received within the tissue receiving port, and a sample tube or “tubular knock out pin” (92) having an open distal end defining a generally circular opening positioned so that a central axis of said sample tube perpendicularly intersects the generally circular opening (Col.17, line 48-51), the sample tube supported on the biopsy device and advanceable within the cutter (Col.13, line 38-41), best seen in Figure 6A-B.

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5. In regards **Claim 3**, Burbank et al disclose a vacuum source in communication with the sample tube (92) (Col.14, line 47-50). In regards to **Claims 4-6**, Burbank et al disclose the sample tube (92) advanced by a pneumatic cylinder (Col.14, line 40-43).

6. In regards to **Claim 7**, Burbank et al disclose an apparatus for advancing and retracting the cutter (68) within the biopsy needle. Specifically, Burbank et al disclose an "inner cutter linear driver" (88) to move the cutter proximally and distally, best seen in Figure 2 (Col.14, line 61-64). In regards to **Claim 8**, Burbank et al disclose an apparatus for advancing and retracting the sample tube (92) within the cutter (68), referred to as "tubular knock out pin linear driver" (112), best seen in Figure 2 (Col.14, line 40-43).

7. In regards to **Claim 9**, Burbank et al disclose the hollow needle (44) comprising a lateral tissue receiving port (46) spaced from the distal end of the needle, best seen in Figure 4.

8. In regards to **Claim 10**, Burbank et al disclose the sample tube (92) comprising a vacuum lumen and a sample lumen. In particular, the vacuum lumen is defined as the proximal portion of said sample tube adjacent to a vacuum connection (Col.13, line 48-49) and the sample lumen is defined as the distal portion that is first to contact the sample (Col.15, line 17-21).

9. In regards to **Claim 13**, Burbank et al disclose a rotating journal for rotating and advancing the cutter. The rotating journal is defined as the "cannular inner cutter elongate indexing gear" (72), which is connected to "cannular inner cutter drive motor" (80) and "inner cutter linear driver" (88) to rotate and advance the cutter, respectively, best seen in Figure 2 (Col.13, line 28-37; Col.18 line 22-24).

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10. In regards to **Claim 16**, Burbank et al disclose a biopsy device comprising:

a hollow biopsy needle (44) having a lateral tissue receiving port (46);

a hollow cutter (68) advanceable within the biopsy needle to sever tissue received within the tissue receiving port;

a sample tube or “tubular knock out pin” (92) having an open distal end defining a distal opening defining a generally circular plane transversely intersecting a central axis of said sample tube, a proximal end in communication with a source of vacuum (Col.14, line 47-50), said sample tube releaseably supported on the biopsy device and advanceable within the cutter;

a drive mechanism for advancing and rotating the cutter within the biopsy needle comprising an internally threaded, rotatably driven component for advancing and rotating the cutter, referred to as “cannular inner cutter collet” (762), best seen in Figure 17 (Col.19, line 49-54).

11. In regards to **Claim 17**, Burbank et al disclose a method of obtaining a tissue sample comprising the steps of:

drawing tissue into a tissue receiving port (546) of a hollow biopsy needle (544);

advancing a hollow cutter (568) in the needle to sever a tissue sample;

advancing a hollow sample tube (578), which includes “sample cassette” (40), in the cutter to position the tissue sample in the sample tube, wherein the hollow sample tube has an open distal end comprising a distally facing opening defined by the distalmost perimeter of the open distal end, best seen in Figure 15A, wherein the tissue sample is axially received in the

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hollow sample tube through the opening at the open distal end of the hollow sample tube during the act of advancing the hollow sample tube (Col.19, line 6-23).

12. In regards to **Claim 18**, Burbank et al disclose a method of stacking multiple samples within the sample tube (578) wherein tissue samples are stacked within the “tissue containment chambers” (120) of sample cassette (40), best seen in Figure 8.

13. In regards to **Claim 19**, Burbank et al disclose a method comprising providing a vacuum through the sample tube (578) (Col.15, line 6-8). In regards to **Claim 20**, Burbank et al disclose a method comprising providing axial vacuum in the cutter with at least one sample disposed the sample tube (Col.15, line 6-8; Col.16, line 40-46), specifically, within the sample cassette (40) of said sample tube.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. **Claims 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al. Burbank et al disclose a sample tube (92) but do not disclose said sample tube comprising a tube wall feature for retaining tissue samples. However, Burbank et al do disclose modifying components of said biopsy device, such as said hollow cutter (68) to include a notch or “tissue receiving port” to retain tissue, best seen in Figure 12A or 14A. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the

sample tube of Burbank et al to include a tube wall featuring comprising a notch disposed adjacent the distal end to further help retain tissue.

16. **Claims 14-15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al in view of Tsonton et al (US Pub No. 2004/0077972). Burbank et al disclose a cutter (60) but do not disclose the cutter having at least one hole extending through an outer surface of the cutter and spaced from a distal end. Tsonton et al disclose a biopsy probe including a stylet with radially-oriented through holes near the distal end to maintain fluid communication between the vacuum lumen chamber (64) and the cutter lumen (56) (§ 0078). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the cutter of Burbank et al to include at least one or a plurality of holes extending through the cutter and spaced from the distal end, as taught by Tsonton et al, to maintain fluid vacuum communication between the various lumens (Figure 7).

Response to Arguments

17. Applicant's arguments with respect to Claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN
8/31/2006

zen


MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700